**Opening Statement of the Honorable Joe Pitts**
**Subcommittee on Health**
**Hearing on "Reviewing FDA's Implementation of FDASIA"**
**November 15, 2013**

*(As Prepared for Delivery)*

The Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law on July 9, 2012.

The purpose of the bill was to bring predictability, consistency, and transparency to FDA's regulation of drugs and devices.

To that end, FDASIA reauthorized two successful user fee programs, the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee Act (MDUFA) scheduled to expire at the end of fiscal year 2013.

It also authorized two new user fee programs for generic drugs (GDUFA) and biosimilars (BSUFA).

In each case, industry negotiated a level of user fees to be paid to FDA in return for the agency meeting agreed upon performance and accountability metrics.

Additionally, FDASIA permanently reauthorized the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, reformed both the drug and medical device regulatory processes, addressed drug supply chain and drug shortage issues, and incentivized the development of new antibiotic drugs, among other provisions.

The bill represents a bipartisan success, not only for our committee but for Congress as a whole. It passed the House by voice vote and passed the Senate by a vote 92 to 4.

Now, over a year later, we are here to examine whether the law has been a success for the American people, resulting in safer drugs and devices, faster approval times, and more consistency and predictability in the process.

There is great congressional interest not only in the overall implementation of FDASIA, but also in the day-to-day operational challenges and successes. And, I would like to congratulate Dr. Woodcock for what I understand is significant progress in the Center for Drug Evaluation and Research.

I would like to welcome both Dr. Janet Woodcock and Dr. Jeffrey Shuren to the Subcommittee.

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